~~UNDER SEAL~~ UNSEALED PER ORDER OF 9/13/11 - GBL

FILED

2010 OCT -8 P 3:55

CLERK US DISTRICT COURT
ALEXANDRIA, VIRGINIA

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA

UNITED STATES OF AMERICA *ex rel.* STEVEN G. KLOTZ, the DISTRICT of COLUMBIA *ex rel.* STEVEN G. KLOTZ, CALIFORNIA *ex rel.* STEVEN G. KLOTZ, COLORADO *ex rel.* STEVEN G. KLOTZ, CONNECTICUT *ex rel.* STEVEN G. KLOTZ, DELAWARE *ex rel.* STEVEN G. KLOTZ, FLORIDA *ex rel.* STEVEN G. KLOTZ, GEORGIA *ex rel.* STEVEN G. KLOTZ, HAWAII *ex rel.* STEVEN G. KLOTZ, ILLINOIS *ex rel.* STEVEN G. KLOTZ, INDIANA *ex rel.* STEVEN G. KLOTZ, LOUISIANA *ex rel.* STEVEN G. KLOTZ, MASSACHUSETTS *ex rel.* STEVEN G. KLOTZ, MICHIGAN *ex rel.* STEVEN G. KLOTZ, MINNESOTA *ex rel.* STEVEN G. KLOTZ, MONTANA *ex rel.* STEVEN G. KLOTZ, NEVADA *ex rel.* STEVEN G. KLOTZ, NEW HAMPSHIRE *ex rel.* STEVEN G. KLOTZ, NEW JERSEY *ex rel.* STEVEN G. KLOTZ, NEW MEXICO *ex rel.* STEVEN G. KLOTZ, NEW YORK *ex rel.* STEVEN G. KLOTZ, NORTH CAROLINA *ex rel.* STEVEN G. KLOTZ, OKLAHOMA *ex rel.* STEVEN G. KLOTZ, RHODE ISLAND *ex rel.* STEVEN G. KLOTZ, TENNESSEE *ex rel.* STEVEN G. KLOTZ, TEXAS *ex rel.* STEVEN G. KLOTZ, VIRGINIA *ex rel.* STEVEN G. KLOTZ, WISCONSIN *ex rel.* STEVEN G. KLOTZ, and STEVEN G. KLOTZ, individually,

Plaintiffs

v.

SHIRE PHARMACEUTICALS, INC., SHIRE U.S. HOLDINGS, INC., and SHIRE, PLC.

Defendants.

CASE NO.: 1:10CV1137 (GBL/JFA)

~~**FILED IN CAMERA**~~
~~**UNDER SEAL**~~

JURY TRIAL DEMANDED

COMPLAINT

Plaintiff-Relator Steven G. Klotz, M.D. ("Relator"), by and through his undersigned attorneys, on behalf of himself, the United States of America (the "United States") and the

1

District of Columbia, the State of California, the State of Colorado, the State of Connecticut, the State of Delaware, the State of Florida, the State of Georgia, the State of Hawaii, the State of Illinois, the State of Indiana, the State of Louisiana, the Commonwealth of Massachusetts, the State of Michigan, the State of Minnesota, the State of Montana, the State of Nevada, the State of New Hampshire, the State of New Jersey, the State of New Mexico, the State of New York, the State of North Carolina, the State of Oklahoma, the State of Rhode Island, the State of Tennessee, the State of Texas, the Commonwealth of Virginia, and the State of Wisconsin (collectively "Plaintiff States") avers as follows for his Complaint against Shire Pharmaceuticals, Inc., its corporate parent Shire U.S. Holdings, Inc., and the ultimate owner of all Shire entities Shire, PLC (collectively "Shire" or the "Defendants") based upon personal knowledge and relevant documents:

I. INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America and the Plaintiff States arising from false and/or fraudulent records, statements and claims made, used and caused to be made, used or presented by Defendants and/or their agents, employees and co-conspirators in violation of the Federal Civil False Claims Act, 31 U.S.C. §3729 *et seq.*, as amended ("the FCA" or "the Act") and its state-law counterparts: the District of Columbia Procurement Reform Amendment Act, D.C. Code Ann. §§1-1188.13 *et seq.*; the California False Claims Act, Cal. Gov Code §12650 *et seq.*; the Colorado Medicaid False Claims Act, Colo. Rev. Stats. §§ 25.5-4-305 *et seq.*; the Connecticut False Claims Act, Conn. Gen. Stats. §§ 17b-301(a) *et seq.*: the Delaware False Claims and False Reporting Act, 6 Del. C. §1201 *et seq.*; the Florida False Claims Act, Fla. Stat. Ann. §68.081 *et seq.*; the Georgia State False Medicaid Claims Act, Ga. Code 49-4-168 *et seq.*; the Hawaii False Claims Act, Haw. Rev.

Stat. §661-21 *et seq.*; the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. §175/1-8; the Indiana False Claims and Whistleblower Protection Act, Indiana Code 5-11-5.5 *et seq.*; the Louisiana False Claims Act, La. Rev. Stat. Ann. § 46:439.1 *et seq.*; the Massachusetts False Claims Law, Mass. Gen. Laws ch. 12 §5 *et seq.*; the Michigan Medicaid False Claim Act, MCL 400.611 § 10a *et seq.* Michigan Public Acts, 1977 PA 72, as amended by 1984 PA 333, as amended by 2005 PA 337, as amended by 2008 PA 421; the Minnesota False Claims Act, Minn. Stat. §§ 15C.01 *et seq.*; the Montana False Claims Act, 2005 Mont. Code, Ch. 465; the Nevada False Claims Act, Nev. Rev. Stat. Ann. §§357.010 *et seq.*; the New Hampshire False Claims Act, § 167:61-b *et seq.*; the New Jersey False Claims Act, N.J. STAT. § 2A:32C-1; the New Mexico Medicaid False Claims Act, N.M. Stat. Ann.§ 27-2F-1 *et seq.*; the New Mexico Fraud Against Taxpayers Act , N.M. Stat. § 44-9-1 *et seq.*; the New York False Claims Act, State Finance Law. §187 *et seq.*; the North Carolina False Claims Act, N.C. Gen. Stat §§ 1-605 *et seq.*; the Oklahoma Medicaid False Claims Act, 63 Okla. Stat. § 5053, *et seq.*; the Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1, *et seq.*; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§71-5-181 *et seq.*; the Tennessee False Claims Act Tenn. Code Ann. § 4-18-101 *et seq.*; the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§36.001 *et seq.*; the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§8.01-216.1 *et seq.*; and the Wisconsin False Claims for Medical Assistance Act, WIS. STAT. § 20.931, *et seq.*

2. The instant matter arises in principal part from Defendants' nationwide, deceptive and dangerous off-label marketing and promotional practices for their drug Intuniv, which is indicated for the treatment of Attention Deficit Hyperactivity Disorder ("ADHD") in children and adolescents aged 6 to 17. Defendants, however, have devised and successfully implemented a marketing campaign calculated to increase primary care physicians' and psychiatrists' "off-label"

use of Intuniv, in various doses, to treat the far broader category of patients suffering from Oppositional Defiant Disorder ("ODD") for which the current standard of care treatment is psychotherapy and training for the child and the parents. The use of Intuniv to treat children suffering from ODD has not received FDA approval and is not supported by the medical compendia DRUGDEX, the American Hospital Formulary Service Drug Information or the United States Pharmacopeia-Drug Information. Defendants' illegal conduct has been ongoing since at least approximately 2008, when Defendants engaged experts in child psychiatry, including the Relator, to participate in "surveys," which were nothing more than thinly veiled marketing efforts that sought information concerning the prospective prescribing habits of these physicians, in an effort to promote Intuniv for the off-label treatment of ODD. These "surveys" could be accessed by doctors on-line at http://www.PCN.com and included questions intended to "seed the market" for the use of the soon-to-be released drug Intuniv for the off-label treatment of ODD. As a direct result of Defendants' improper off-label and misleading marketing practices for Intuniv, health insurance programs funded by the United States and the Plaintiff States including, but not limited to Medicaid, Medicare, Medicare Part D, the Railroad Retirement Medicare Program, Federal Employees Health Benefit Programs, Tri-Care (formerly CHAMPUS), CHAMPVA, State Legal Immigrant Assistance Grants and the Indian Health Service (collectively the "Programs") paid false or fraudulent Intuniv reimbursement claims for prescriptions written to the Programs' beneficiaries for off-label, non-medically accepted indications. The United States and the Plaintiff States would not have paid such false claims but for Defendants' illegal and fraudulent conduct.

3. Moreover Defendants' conduct endangered the health of the Programs' beneficiaries by placing them at needless risk of somnolence, headache, sedation, dizziness,

drowsiness, fatigue, dry mouth, digestive tract problems, upper abdominal pain, constipation, hypotension, and other adverse events, including potentially death, associated with the use of Intuniv that were known to Defendants at all times relevant to this Complaint, but which Defendants intentionally obfuscated to protect their windfall of Intuniv sales revenues.

4. The FCA provides that any person who knowingly submits, or causes the submission of, a false or fraudulent claim to the U.S. Government for payment or approval is liable for a civil penalty of up to $11,000 for each such claim, plus three times the amount of the damages sustained by the Government. Liability attaches when a defendant knowingly seeks payment, or causes others to seek payment, from the Government that is unwarranted.

5. The Act allows any person having information about a false or fraudulent claim against the Government to bring an action for himself and the Government, and to share in any recovery.

6. Based on these provisions, Plaintiff-Relator Steven G. Klotz, M.D., seeks through this action to recover on behalf of the United States and the Plaintiff States (which have laws authorizing similar *qui tam* actions) damages and civil penalties arising from Defendants' making or causing to be made false or fraudulent records, statements and/or claims for reimbursement for ineligible Intuniv prescriptions as the direct and foreseeable consequence of Defendants' off-label marketing of the drugs, including for the treatment of ODD. Defendants did not directly submit claims for prescription drugs to federal and state health insurance programs, however, Defendants knew -- and in fact it was their goal -- that their illegal off-label and misleading marketing practices would cause the submission of thousands of claims to government-funded health programs for prescriptions that were not eligible for program reimbursement.

7. Defendants' unlawful off-label marketing campaign for Intuniv was accomplished and continues to be accomplished through the use of Defendants' sales representatives, promotional literature, websites, direct to physician educational programs and speaker dinners, all of which have been witnessed by Relator. As a direct result of Defendants' efforts to falsely market Intuniv well-beyond its narrow FDA-approved parameters and for the treatment of ODD, sales of Intuniv in the United States since the drug's approval in September 2009 have been exponentially greater than they would otherwise be. That is because while the market is crowded with cheaper, more effective medications for ADHD, Defendants face no competition for off-label use of Intuniv to treat ODD because no medicine has ever been approved by the FDA to treat ODD. Thus, Relator estimates that a significant percentage of all sales of Intuniv, perhaps as great as 90% of all sales of Intuniv, are linked to the off label marketing of that drug, and not to sales for its approved use.

8. As part of its unlawful, off-label marketing campaign for Intuniv, Shire and its sales, marketing and promotional teams, internal and external, have coined the phrase "ADHD Spectrum," and used that misleading term to blur the lines between ADHD and ODD. On their website, and in their promotional and educational office visits, and through their sales representatives, Shire discusses the Connor's rating scale as evidence of Intuniv's benefit for ADHD and ODD, the "ADH Spectrum." In fact, the Connor's rating scale is primarily a screening measure, not an outcomes measure. Defendants, however, have misused the Connor's rating scale by representing that because Intuniv treats some of the symptoms shared by ADHD and ODD, it treats ODD. The blending of the ADHD and ODD subsections of the Connor's scale in this way is nothing more than a marketing ploy done solely for Shire's own economic benefit and is not supported by science. Further, Shire's FDA approved insert refers to ADHD Rating

Scale – IV (ADHD – RS), whereas instead much of their lecture and promotional visits use/misuse the Connor's rating scale.

9. Relator Steven G. Klotz, M.D. brings this action on behalf of the United States and the Plaintiff States to recover the tens of millions of dollars Medicaid, Medicare, Medicare Part D, the Railroad Retirement Medicare Program, Federal Employees Health Benefit Programs, Tri-Care (formerly CHAMPUS), CHAMPVA, State Legal Immigrant Assistance Grants and the Indian Health Service have been fraudulently induced to pay as a result of false and/or fraudulent Intuniv reimbursement claims submitted by, and caused to be submitted by, Defendants.

10. Relator Steven G. Klotz, M.D., is a credentialed child psychiatrist who is also experienced in adult and adolescent psychiatry. Relator Klotz has filed the instant *qui tam* suit seeking to redress harm to the United States and the Plaintiff States for Intuniv written off-label and/or for non-medically accepted indications that were unlawfully induced by Defendants as a result of their deceptive marketing practices, specifically, the company's off-label marketing of Intuniv to treat ODD.

11. Relator Dr. Klotz is well situated to file this *qui tam* claim. He is lifetime certified by the American Medical Association, the American Psychiatric Association, the American Academy of Child & Adolescent Psychiatry, the American Society for Addiction Medicine, the International Association for Pain and Chemical Dependency and the National Alliance on Mental Illness. Dr. Klotz is actively licensed to practice medicine in Pennsylvania. He is certified to prescribe Intuniv, as well as other ADHD drugs to children, and has treated over 400 children with ADHD using drugs and or therapy as required by the standard of care, and has treated over 150 children for ODD using psychotherapy and training as required by the standard of care.

12. Dr. Klotz resides in the Commonwealth of Pennsylvania where he practices medicine. Dr. Klotz's practice specialties are Adult Psychiatry and Child and Adolescent Psychiatry. Dr. Klotz is also a recognized expert in the diagnosis and treatment of mental illness. He graduated with an A.B. in Chemistry/Biochemistry from Columbia College, Columbia University and a M.D. degree from Mount Sinai School of Medicine. Relator's post-graduate medical training and other education includes: a Fellowship at the Department of Psychiatry, Division of Child and Adolescence Psychiatry at Stony Brook University Hospital; Residencies at Department of Psychiatry, Stony Brook University and Department of Anesthesia at New York University; and an Internship at the Department of Medicine at Beth Israel Medical Center.

13. Dr. Klotz has written scholarly letters/reviews/articles that have been published in numerous respected peer review medical journals, including: The New England Journal of Medicine; Child and Adolescent Psychiatry; Mental Health and APA Abstracts; General Hospital Psychiatry; Journal of Child and Adolescent Psychopharmacology; and Psychiatry Source.

14. At all times relevant to this complaint, Relator has personally witnessed and monitored the effects of Intuniv in patients prescribed the drug. Relator has also personally witnessed and been a target of Defendants' attempts to market Intuniv for the off-label use of treating ODD. First, Relator has attended two dinner talks sponsored by Defendants, one in Philadelphia, Pennsylvania and one in Lancaster, Pennsylvania in which Intuniv was directly marketed to Relator and other physicians to treat ODD -- an off-label use. Relator noted that numerous sales representatives and corporate employees attended these dinner programs and that the marketing of Intuniv for the off-label purpose of treating ODD occurred prior to, during and after the official dinner. In fact, at least one-third of the content of the speaker's talks and one-third of the slides presented during those talks dealt with the off-label use of Intuniv to treat ODD.

Second, Relator has also reviewed Defendant's advertisements, sales slides, educational materials and information posted on its website and found as to each, Defendants have marketed Intuniv for the off-label purpose of treating ODD. Among the ways Defendants do this is by suggesting that there is an "ADHD Spectrum," a newly created term which has no medical meaning, but by which Defendants justify misusing the Connors rating scale and promoting Intuniv off-label. Likewise, on their website for Intuniv, Defendants quote the Connors rating scale presumably for ADHD, but in fact they are using the ODD subsection of the Connors scale and not the ADHD diagnostic screening section. In this way, Defendants are fraudulently representing that Intuniv treats ODD because it treats some of the individual symptoms of ODD that are shared with a diagnosis of ADHD. Further, it constitutes misbranding in and of itself for Shire to market Intuniv as an effective treatment for individual symptoms. Third, Defendants' sales representatives have also pitched Intuniv off-label directly to Relator. For example, Defendants' sale representative Angie Grenier has marketed the off-label use of Intuniv directly to Relator on numerous occasions at both his office and at a clinic where Relator was working. Most recently, on August 13, 2010, Ms. Grenier visited Relator in his office. Others were present at that time in addition to Ms. Grenier and Relator. At that time, Ms. Grenier admitted that Defendants had been marketing Intuniv for the off-label use of treating ODD and disclosed that Defendants would no longer be doing so. Ms. Grenier stated that as of June of 2010, Defendants had withdrawn the "monster-child" advertisements, which had been part of their off-label marketing effort. Ms. Grenier also stated that Defendants told their sales representatives that they were no longer permitted to discuss the so-called ADHD Spectrum Disorders as they did when Intuniv was first launched. After admitting that treatment for ODD was an off-label use of Intuniv, Ms. Grenier went on to describe a recent study that she said showed that patients with ODD did show an

improvement when using Intuniv. Ms. Grenier also suggested that Intuniv could soon be approved for such use. A recent review of the FDA.gov website, however, shows no new, amended or pending applications or approvals for Intuniv use for ODD. Ms. Grenier's persistence in marketing Intuniv for ODD demonstrates her claim that Defendants have ceased all marketing of Intuniv for ODD to be mere lip service. Finally, in a telephone call with investors, Defendants' management stated that they expected Intuniv might be used off-label for ODD.

15. Dr. Klotz's early and unwitting involvement in Defendants' marketing scheme to broaden the market for Intuniv by promoting it to treat ODD, combined with his background in treating ODD in children and adolescents, puts Dr. Klotz in a unique position to uncover Defendants' unlawful misrepresentations regarding the off-label uses of Intuniv. Specifically, Defendants' efficacy claims are not supported by the available scientific research. Knowing that their claims are unsupported, Defendants have deliberately obfuscated, misrepresented or omitted material information to prescribers and others through manipulation of the data, scientific method and facts, to promote the drug for off-label use to treat ODD.

16. Defendant Shire Pharmaceuticals, Inc. ("SPI") is a Delaware Corporation with its residence in Pennsylvania. Since 2008, SPI has overseen the marketing and distribution of Intuniv in the United States, including in the Commonwealth of Virginia. Defendant Shire U.S. Holdings, is the corporate parent of SPI. SPI's primary activities in the United States include the manufacturing, marketing, and distribution of Intuniv. The ultimate owner of all Shire entities is Defendant Shire, PLC, a publicly traded company.

II. JURISDICTION AND VENUE

17. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331, 28 U.S.C. §1367 and 31 U.S.C. §3732, the last of which specifically confers

jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§3729 and 3730. Under 31 U.S.C. §3730(e) as amended, there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint. Relator Klotz, moreover, qualifies under that section of the False Claims Act as an "original source" of the allegations in this Complaint even had such a public disclosure occurred.

18. Upon the filing of this complaint, Relator Klotz shall concurrently serve upon the Attorney General of the United States, the United States Attorney for the Eastern District of Virginia and the Plaintiff States Attorney Generals' offices (or other State offices designated by statute) the complaint and a statement summarizing known material evidence and information related to this Complaint, in accordance with the provisions of 31 U.S.C. §3730(b)(2). The disclosure statement is supported by material evidence. The initial disclosure statement and all documents provided therewith, and all supplements thereto, are incorporated herein by reference.

19. This Court has personal jurisdiction and venue over the Defendants pursuant to 28 U.S.C. §§1391(b) and 31 U.S.C. §3732(a) because those sections authorize nationwide service of process and because each Defendant has minimum contacts with the United States. Moreover, Defendants can be found in, reside, and/or transact business in this District, and SPI, has its principal place of business in this District. This Court has supplemental jurisdiction over the State law claims pursuant to 28 U.S.C. §1367(a).

20. Venue is proper in this District pursuant to 31 U.S.C. §3732(a) because each Defendant transacts business in this judicial district, and acts proscribed by 31 U.S.C. §3729 have been committed by Defendants in this District. Therefore, venue is proper within the meaning of 28 U.S.C. §1391(b) & (c) and 31 U.S.C. §3732(a).

III. BACKGROUND

A. The FDA Approved the Use of Intuniv Only for the Treatment of ADHD.

21. On or about September 6, 2009, the United States Food and Drug Administration approved Intuniv® for the treatment of Attention Deficit Hyperactivity Disorder in children and adolescents aged 6 to 17 years. Intuniv is the brand name of a once-daily formulation of guanfacine – a medication used to treat high blood pressure. There are no other approved uses for Intuniv. Thus the use of Intuniv in the treatment of such diagnoses as Oppositional Defiant Disorder is an off-label use of the drug.

B. Clinical Definitions of Attention Deficit Hyperactivity Disorder and Oppositional Defiant Disorder and Appropriate Treatment

22. ADHD - the treatment of which is the only indicated use for Intuniv – is narrowly defined in the Diagnostic and Statistical Manual of Mental Disorders IV ("DSM IV") as "a persistent pattern of inattention and/or hyperactivity-impulsivity that is more frequently displayed and more severe than is typically observed in individuals at a comparable level of development." DSM IV. In order for a person to be properly diagnosed with ADHD, some symptoms, of either hyperactive-impulsivity or inattention, must have been present before age 7 and must be present in at least two settings, for example, home, work or school. Id.

23. In contrast, ODD can be diagnosed where a patient merely exhibits "an ongoing pattern of disobedient, hostile and defiant behavior toward authority figures which goes beyond the bounds of normal childhood behavior." DSM IV. In order for a person to be properly diagnosed with ODD, the defiance "must interfere with the child's ability to function in school, home, or the community," "cannot be the result of another disorder," and must occur for at least six months.

24. Treating ODD involves several types of psychotherapy and training for the child suffering from the disorder as well as for the parents. The cornerstones of treatment for ODD include: individual and family therapy; parent-child interaction therapy; cognitive problem solving and training; parent training; and social skills training. Proper treatment of ODD, unlike the treatment of ADHD, does not include drug therapy, and Relator is aware of no drug that has been approved for the treatment of ODD.

25. Moreover, the use of Intuniv is contraindicated in ADHD patients who are being treated for ADHD with stimulants. Stimulants are the most common form of drug prescribed for the treatment of ADHD and work by causing a calming effect in those suffering from ADHD. Stimulants, however, cause a rise in blood pressure and heart rate, while Intuniv which is an alpha blocker causes a drop in blood pressure. The combination of a drop in blood pressure and a rise in heart rate is unsafe and among other things can cause dizziness and cardiac arthymia. Thus, using Intuniv in conjunction with stimulants is contraindicated.

26. As set forth below, Defendants have not submitted a supplemental New Drug Application to the FDA for Intuniv in furtherance of obtaining FDA-approval for use of the drug to treat ODD. Defendants' illegal marketing efforts, however, have now caused the drug to be widely prescribed to children suffering only from ODD. Relator is personally aware of cases in which doctors have prescribed Intuniv for use in treating ODD.

C. The FDA Decision Severely Limits the Potential Revenues for On-Label use of Intuniv.

27. Legal on-label marketing of Intuniv would result in only limited revenue potential for Defendants because the FDA-approved on-label use of the drug is for administration to children diagnosed with ADHD. The number of children estimated to be diagnosed with ADHD is only approximately 4% and the approved dosage for the drug is only 1 to 4 mgs per day.

Defendants recognized the limited revenue potential given the relatively small size of the estimated population of patients qualifying for such treatment. Moreover, although Intuniv was only recently approved by the FDA, it has only two years remaining before the expiration of Defendants' regulatory exclusivity on the drug. Even worse for Defendants, the field of drugs approved for the treatment of ADHD is already crowded with generics that are much cheaper than the premium price that Defendants charge for Intuniv.

28. Faced with such potential revenue limiting circumstances, Defendants embarked upon a brazen pattern of off-label promotion reflecting a reckless disregard for patient safety in their quest for increased revenues.

IV. ALLEGATIONS

A. Defendants' Aggressive Marketing Efforts to Grow the Off-Label Markets for Intuniv.

29. Even prior to securing FDA approval for Intuniv, Defendants commenced laying the groundwork for their unlawful off-label marketing campaign for the drug. Defendants' illegal off-label marketing campaign included utilization of its sales representative force, and the creation and distribution of intentionally misleading promotional materials.

30. As noted above, for nearly a year prior to the FDA's approval of Intuniv, Defendants marketed the drug to psychiatrists who treat children and adolescents, including the Relator, under the guise of pre-approval "surveys" allegedly aimed at determining the physicians' prescribing habits. The Defendants promoted their drug as a new medication not only to treat ADHD, but also for patients afflicted with ODD – for which the current standard of care is drug-free psychotherapy and for which no drug has been approved as an effective treatment. To increase the market for Intuniv, Defendants have subtly advanced the use of the drug concomitantly with other ADHD drugs but neglected to disclose the dangers of using Intuniv in

conjunction with psychostimulants – the primary drugs used to treat ADHD. These stimulant drugs, including Defendants' own drug Vyvanse, stimulate the central nervous system but have a calming effect on people with ADHD. These psychostimulants also increase heart rate, and should never be used in conjunction with Intuniv, a drug that is used to control blood pressure, because such use can cause dizziness, heart arrhythmia or worse.

31. Defendants' emphasis on pushing Intuniv to treat ODD has manifested itself in Defendants' print and internet advertising, their so-called "expert learning programs," as well as through direct to physician detailing. At each turn, Defendants have sought to expand the definition of ADHD to include ODD symptoms and have discussed "oppositionality" as a treatable symptom of ADHD. The use of Intuniv for ODD is an off-label use because the FDA never approved the drug for treating ODD and the drug was never studied for that purpose. Accordingly, the approved labeling for Intuniv does not support Defendants' promotion of the drugs for treating ODD and Defendants' promotion of Intuniv for treatment of ODD therefore constitutes an off-label promotion.

32. Defendants' internet claims further advance their efforts to mislead physicians who treat children by falsely claiming that symptoms of ODD are related and part of the diagnostic spectrum of ADHD. This is done through a misuse of the Connors scale, which is a two part scale. The first part is intended to address ADHD symptoms and the second part addresses ODD symptoms. Defendants, however, blur these sections together and represent that because ADHD and ODD share some symptoms and because Intuniv treats those symptoms in ADHD patients, it is an appropriate drug for ODD. This is not the case and is an inappropriate use of the Connors Rating Scale. Intuniv has never been approved to treat ODD.

33. Moreover, to the extent the claim that Intuniv improves any individual symptom of ADHD is unsubstantiated, that claim also misbrands Intuniv in violation of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 352(a) and 321(n).

34. In late fall 2009, the Relator attended a promotional dinner program sponsored by Defendants in conjunction with the launch of Intuniv in Philadelphia, Pennsylvania. The physician retained by Defendants to promote Intuniv at this event stated that ODD was the real target of Defendants' drug, and the slides used during the promotion of Intuniv included an entire section on ODD. The crux of the presentation was to promote the off-label use of Intuniv specifically for the treatment of ODD. In fact, Defendants' off-label marketing of Intuniv was so blatant at this dinner that approximately one-third of the overall presentation was devoted to Intuniv for this off-label use.

35. Defendants have also expanded the market for off-label use of Intuniv by marketing it for the use of ODD not only to child therapists, but also to pediatricians and primary care physicians who see a much greater volume of child patients.

36. Defendants' financial incentives to engage in the illegal off-label promotion of Intuniv for the treatment of ODD stem from the statistics that estimate the percentage of children suffering from ODD – for which there is no FDA-approved drug – to be approximately 16%. By comparison, the estimated percentage of children with ADHD is estimated at approximately only 4%. Thus a diagnosis of ODD in children is four times as common as a diagnosis of ADHD in children. Moreover, defendants are also motivated by the impending loss of FDA regulatory exclusivity.

37. On multiple occasions, between 2008 and the filing of this Complaint, Defendants' sales representatives made unsolicited marketing presentations to Relator in which

they encouraged Relator to prescribe Intuniv for ODD, an off-label use that is not a medically accepted indication.

38. Defendants engaged in this illegal off-label marketing of Intuniv in order to increase Defendants' revenue in excess of the comparatively limited revenue potential from the mere on-label use of Intuniv. Defendants engaged in these illegal off-label marketing promotions with the purpose and intent of causing government-funded healthcare programs such as Medicare and Medicaid and Medicare Part D to fund the purchases of off-label uses of these drugs and the associated physician services, despite the knowledge that such claims were ineligible for reimbursement.

39. As a result of Defendants' off-label promotion of Intuniv, health care programs funded by the United States and the Plaintiff States, including Medicare Part D and Medicaid, have paid to purchase Intuniv prescribed off-label to beneficiaries of those programs. These prescriptions were ineligible for reimbursement, as is set forth *supra*.

40. Indeed, Defendants' illegal off-label marketing promotions have been enormously successful. Since their FDA approval in September 2009, Intuniv has gained tremendous market share, with U.S. sales in the first quarter of 2010 of 34.5 million dollars.

B. Undisclosed Side Effects and Dangers Associated with Intuniv

41. By aggressively seeking to expand the off-label use of Intuniv, Defendants deliberately chose to increase revenues at the expense of patient safety.

42. Specifically, Defendants minimized the adverse side effects of Intuniv in their presentations to doctors and purposefully underestimated how much those side effects can interfere with the lives of the children who take them. They also encourage the use of Intuniv in

conjunction with other ADHD medications, despite the fact that such use is contraindicated and may cause serious side effects including dizziness and heart arhythmia.

V. APPLICABLE LAW

A. The FDA Regulatory Scheme

43. Under the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301-97, new pharmaceutical drugs cannot be marketed in the United States unless the sponsor of the drug demonstrates to the satisfaction of the Food and Drug Administration ("FDA") that the drug is safe and effective for each of its intended uses. 21 U.S.C. §355 (a) & (d). Approval of the drug by the FDA is the final stage of a multi-year process of study and testing.

44. The FDA does not approve a drug for treatment of sickness in general. Instead, a drug is approved for treatment of a specific condition, for which the drug has been tested in patients. The specific approved use is called the "indication" for which the drug may be prescribed. The FDA will specify particular dosages determined to be safe and effective for each indication.

45. The indication and dosages approved by the FDA are set forth in the drug's labeling, the content of which is also reviewed and approved by the FDA. 21 U.S.C. §§352, 355(d). An example of the drug's labeling is the printed insert in the drug's packaging. The FDA will only approve the new drug application if the labeling conforms to the uses and dosages that the FDA has approved. 21 U.S.C. §355(d).

46. Under the Food and Drug Administration Modernization Act of 1997 ("FDAMA"), if a manufacturer wishes to market or promote an approved drug for alternative uses - i.e., uses not listed on the approved label - the manufacturer must resubmit the drug for another series of clinical trials similar to those for the initial approval. 21 U.S.C. §360aaa(b) & (c). Until

subsequent approval of the new use has been granted, the unapproved use is considered to be "off-label." "Off-label" refers to the use of an approved drug for any purpose, or in any manner, other than what is described in the drug's labeling. Off-label use includes treating a condition not indicated on the label, treating the indicated condition at a different dose or frequency than specified in the label, or treating a different patient population (e g., treating a child when the drug is approved to treat adults).

47. Although the FDA is responsible for ensuring that a drug is safe and effective for the specific approved indication, the FDA does not regulate the practice of medicine. Once a drug is approved for a particular use, the FDA does not prohibit doctors from prescribing the drug for uses that are different from those approved by the FDA.

48. Although physicians may prescribe drugs for off-label usage, the law prohibits drug manufacturers from marketing or promoting a drug for a use that the FDA has not approved. Specifically, under the Food and Drug laws, (1) a manufacturer may not introduce a drug into interstate commerce with an intent that it be used for an off-label purpose, and (2) a manufacturer illegally "misbrands" a drug if the drug's labeling (which includes all marketing and promotional materials relating to the drug) describes intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§331, 352.

49. An off-label use of a drug can cease to be off-label only if the manufacturer submits a supplemental application and demonstrates to the satisfaction of the FDA that the product is safe and effective for the proposed new use. 21 U.S.C. §360aaa(b)&(c).63.

50. In addition to prohibiting manufacturers from directly marketing and promoting a product's off-label uses, Congress and the FDA have also sought to prevent manufacturers from employing indirect methods to accomplish the same end. For example, Congress and the FDA

have attempted to regulate two of the most prevalent indirect promotional strategies: (1) manufacturer dissemination of medical and scientific publications concerning the off-label uses of its products, and (2) manufacturer support for Continuing Medical Education (CME) programs that focus on off-label uses. With regard to the first practice - disseminating written information - the FDAMA only permits a manufacturer to disseminate information regarding off-label usage in response to an "unsolicited request from a health care practitioner." 21 U.S.C. §360aaa-6 (emphasis added). In any other circumstance, a manufacturer is permitted to disseminate information concerning the off-label uses of a drug only after the manufacturer has submitted an application to the FDA seeking approval of the drug for the off-label use; has provided the materials to the FDA prior to dissemination; and the materials themselves must be in an unabridged form and must not be false or misleading. 21 U.S.C. §§ 360aaa(b) & (c); 360aaa-1.

51. With regard to manufacturer involvement in CME programs, the FDA's examination of these practices led to publication of an agency enforcement policy in 1997 entitled, "Guidance for Industry: Industry-Supported Scientific and Educational Activities," 62 Fed. Reg. 64,074, 64,093, 1997 WL 740420 (F.R.) (1997). This guidance document states that CME programs must be truly independent of the drug companies, and sets forth a number of factors that the FDA will consider in determining whether a program is "free from the supporting company's influence and bias." *Id.* These factors include, among others, an examination of the relationship between the program provider and supporting company, the company's control of content and selection of presenters, whether there is a meaningful disclosure of the company's funding and role in the program, whether multiple presentations of the same program are held, whether the audience is selected by the sales and marketing department of the company, and whether information about the supporting company's product is disseminated after the initial

program other than in response to an unsolicited request. *Id.* The promotion of off-label drug uses at a CME program which fails this test of "independence" violates Congress' off-label marketing restrictions.

52. In sum, the off-label regulatory scheme protects patients and consumers by insuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific governmental body, the FDA.

53. Defendants, unable to control and bolster revenues for Intuniv by just submitting prescription drug reimbursement claims to Medicaid and Medicare and the other government-funded healthcare programs named herein; instead launched a campaign intended to increase Government-funded off-label purchases of these narcotics by defrauding physicians and psychiatrists, to prescribe Intuniv for non-medically accepted indications. The natural, intended and foreseeable consequence of such unlawful, premeditated conduct caused such physicians and/or pharmacists to submit claims to publicly-funded health plans that were ineligible for reimbursement pursuant to these programs' regulations.

54. Each such claim Defendants knowingly caused to be submitted under these false pretenses in derogation of the labeling and misbranding laws, and each false statement it made to cause claims for Intuniv to be paid, constitutes a false claim for which Defendants are accountable under the Federal False Claims Act and the analogous laws of the Plaintiff States.

B. Regulations Restricting Reimbursement for Off-label Prescription Drug Uses by Government-Funded HealthCare Programs.

55. While physicians are free to prescribe drugs off-label, pharmaceutical companies are prohibited by law from promoting drugs for uses and dosages not approved by the FDA. In addition, payment for off-label uses of prescription drugs by government-funded healthcare programs is highly regulated and restricted pursuant to the laws set forth below.

56. When drug manufacturers promote their drugs off-label, this causes the submission of false claims to *inter alia*, government funded health care programs.

VI. GOVERNMENT FUNDED HEALTHCARE PROGRAMS DAMAGED BY PAYING FALSE INTUNIV CLAIMS

57. Title XIX of the Social Security Act is a program that provides medical assistance for certain individuals and families with low incomes and resources. The program, known as Medicaid, became law in 1965 as a jointly funded cooperative venture between the Federal and State governments to assist States in the provision of adequate medical care to eligible needy Americans. Among the groups of people served by Medicaid are eligible low-income parents and children. Among the health benefits funded primarily by Medicaid, up until January 1, 2006, was funding for the prescription drug needs of the Program's beneficiaries. On January 1, 2006, Medicare Part D went into effect.

58. A State must have a plan for medical assistance that has been approved by the Centers for Medicare and Medicaid Services (CMS), which administers the program on behalf of the Secretary of Health and Human Services to participate in the Medicaid program. The state plan must specify, among other things, the specific kinds of medical care and services that will be covered. 42 U.S.C. § 1396a(a)(10) and (17). If the plan is approved by the Secretary, the State thereafter is eligible for federal financial participation, *i.e.*, reimbursement by the federal government for a specified percentage of the amounts that qualify as medical assistance under the state plan. *Id.* at §§ 1396b(a)(I), 1396d(b).

59. States are accorded a broad measure of flexibility in tailoring the scope and coverage of their plans to meet the particular needs of their residents and their own budgetary and other circumstances. While the Medicaid Act requires States to provide certain basic services, the

Act permits, but does not require, States to cover prescription drugs, although most States choose to do so. 42 U.S.C. § 1396d(a)(12).

60. In 1990, Congress enacted the Medicaid Drug Rebate Statute, codified at 42 U.S.C. §1396r-8, to "establish a rebate mechanism in order to give Medicaid the benefit of the best price for which a manufacturer sells a prescription drug to any public or private purchaser." H.R. Rep. No. 881, 101st Cong., 2d Sess. 96 (1990). That statute prohibits federal financial participation for covered outpatient drugs unless there is a rebate agreement in effect under section 1396r-8. See 42 U.S.C. §§ 1396b(i)(10)(A) and 1396r-8(a)(I). Once a drug manufacturer has entered into a rebate agreement for a covered outpatient drug, a State is generally required to cover that drug under the state plan.

61. However, there are several provisions of the Medicaid Act that permit a State to exclude or restrict coverage. 42 U.S.C. § 1396a(a)(54); H.R. Rep. No. 881 at 97,98. A State may restrict from coverage or exclude altogether certain drugs or classes of drugs, or certain medical uses, such as drugs used for, among other things, cosmetic purposes. 42 U.S.C. § 1396r-8(d)(l)(B)(ii). Relevant hereto is the provision which permits a State to exclude or restrict coverage of a drug where "the prescribed use is not for a medically accepted indication." 42 U.S.C. § 1396r-8(d)(l)(B)(i).

62. Under the statute, a "covered outpatient drug" includes a drug dispensed by prescription and approved as safe and effective under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 355 & 357. It does not include "a drug or biological use for a medical indication which is not a medically accepted indication." 42 U.S.C. § 1396r-8(k)(2), (3).

63. The statute defines "medically accepted indication" as: any use for a covered outpatient drug which is approved under the [FDCA], or the use of which is supported by one or

more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i) of this section. Id. at § 1396r-8(k)(6).

64. The three compendia identified in subsection (g)(I)(B)(i) are the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information, and the DrugDex Information System. *Id.* at § 1396r-8(g)(l)(B)(i).

65. Upon information and belief, the most commonly-available of these compendia, DrugDex, does not support the off-label uses for Intuniv promoted by Defendants.

66. Similarly, off-label indications qualify as "medically accepted indications" for Medicare reimbursement if they appear on the identified drug reporting compendia.

67. DrugDex is a proprietary information service provided by a division of the Thomson Reuters Corporation. DrugDex is unique in that it is designated by the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. 352(f)(1), the FDA Modernization Act of 1997 and FDA implementing regulations as a statutory compendium, and is the only such compendium that continues to publish detailed clinical information pertaining to pharmaceutical products.

68. Discussions of "therapeutic uses" for all drugs approved by the FDA are found within Section 4.5 of the DrugDex entry for that drug. These reviews include both FDA-approved and off-label indications. Material cited with respect to off-label indications can be used by the Centers for Medicaid and Medicare (CMS) in making decisions about the eligibility of claims made for reimbursement of the cost of program beneficiaries' prescription drugs. The specific content of DrugDex recommendations is therefore critical.

69. DrugDex assigns to each evaluated therapeutic use a "Class" which identifies whether a drug is recommended and/or efficacious for that use. Uses that DrugDex lists as Class

III are not considered medically accepted indications for the purposes of determining coverage policy.

70. Defendants knew or should have known of the Medicaid regulations governing prescription drug reimbursement.

71. At all times relevant to this Complaint, the United States and the Plaintiff States were unaware of the unlawful manner in which Defendants promoted Intuniv throughout the United States.

72. Hereinafter off-label and non-medically accepted indication shall be used interchangeably.

73. In addition to Medicaid, the federal government reimburses a portion of the cost of prescription drugs under several other health care programs, including but not limited to Medicare, Medicare Part D, the Railroad Retirement Medicare Program, Federal Employees Health Benefit Programs, Tri-Care (formerly CHAMPUS), CHAMPVA, the Federal Employees Compensation Act Program, the Bureau of Prisons, State Legal Immigrant Assistance Grants and the Indian Health Service, the Department of Defense, the Department of Labor, and the Public Health Service Entities. as alleged below. As alleged below, these programs operate in similar ways to the Medicare program. For example, the VA and CHAMPUS/Tri-care operate in substantially similar ways to the Medicare and Medicaid programs, but primarily for the benefit of military veterans, their spouses (or widowed spouses) and other beneficiaries.

74. Coverage of off-label drug use under these programs is similar to coverage under the Medicaid program. See, eg., TRICARE Policy Manual 6010.47-M, Chapter 7, Section 7.1 (B) (2) (March 15, 2008); CHAMPVA Policy Manual, Chapter 2, Section 22.1, Art. II (A)(2) (June 6, 2008).

A. Medicare and Medicare Part D

75. Medicare is a government financial health insurance program administered by the Social Security Administration of the United States. The health insurance provided to beneficiaries of the Medicare insurance program is paid in whole or in part by the United States. Medicare was promulgated to provide payment for medical services, durable medical equipment and other related health items for individuals 65 and over. Medicare also makes payments for certain health services provided to additional classes of individual healthcare patients pursuant to federal regulation.

76. The Medicare Prescription Drug Improvement and Modernization Act of 2003 added prescription drug benefits to the Medicare program. The Medicare Prescription Drug benefit covers all drugs that are considered "covered outpatient drugs" under 42 U.S.C. §1396r-8(k) (as described above).

77. The first stage of the Medicare program, from May 2004 through December 2005, permitted Medicare beneficiaries to enroll in a Medicare-approved drug discount card program.

78. On December 8, 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA"). Title I of the MMA created new outpatient prescription drug coverage under Medicare ("Medicare Part D").

79. Medicare Part D went into effect on January 1, 2006. The Program is administered by the United States Department of Health and Human Services, Centers for Medicare and Medicaid ("CMS"). For "dual eligibles," defined as individuals who received prescription drug coverage under Medicaid in addition to Medicare coverage for other health care in 2005, enrollment in Medicare Part D was compulsory. Such beneficiaries were automatically

switched to Part D plans for 2006 and commenced receiving comprehensive prescription drug coverage under Medicare Part D.

80. Coverage of prescription drugs under Medicare Part D is subject to the same regulations as coverage under the Medicaid Program described above.

81. As a direct, proximate and intended result of the conduct of the Defendants' alleged herein in violation of the Federal False Claims Act and the analogous laws of the Plaintiff States, the Medicare and Medicare Part D programs have been damaged.

B. The Railroad Retirement Medicare Program

82. The Railroad Retirement Medicare program is authorized by the Railroad Retirement Act of 1974, at U.S.C.A. §231 *et seq*. It is administered through the United States Railroad Retirement Board, "RRB," and furnishes Medicare coverage to retired railroad employees.

83. As a direct, proximate and intended result of the conduct of the Defendants' alleged herein in violation of the federal false claims act and the analogous laws of the Plaintiff States, the RRB program has been damaged.

C. Federal Employee Health Benefit Plans

84. The Federal Employees Health Benefits Program ("FEHBP") is administered by the United States Office of Personnel Management ("OPM") pursuant to 5 U.S.C.A §8901 *et seq.* and provides health care coverage to federal employees, retirees and their dependants and survivors.

85. As a direct, proximate and intended result of the conduct of the Defendants' alleged herein in violation of the Federal False Claims Act and the analogous laws of the Plaintiff States, the FEHBP program has been damaged.

D. Tri-Care

86. The Tri-Care program, formerly, CHAMPUS, is administered by the United States Department of Defense through its component agency, CHAMPUS, under the authority of 10 U.S.C. §§1701-1106. It is a health care program that provides for care in civilian facilities for members of the uniformed services and their dependents. Pursuant to 38 U.S.C. §8126, and the regulations based there on, drugs furnished by drug manufactures to the Department of Defense must be furnished at the best price.

87. As a direct, proximate and intended result of the conduct of the Defendants' alleged herein in violation of the federal false claims act and the analogous laws of the Plaintiff States, the Tri-care program has been damaged.

E. The Veterans Administration

88. The Civilian Health and Medical Program of the Department of Veterans Affairs ("CHAMPVA") is a comprehensive health care program in which the VA shares the cost of covered health care services and supplies with eligible beneficiaries. The program is administered by Health Administration Center and its offices are located in Denver, Colorado. In general, the CHAMPVA program covers most health care services and supplies that are medically and psychologically necessary.

89. Due to the similarity between CHAMPVA and the Department of Defense ("DoD") Tri-Care program, the two are often mistaken for each other. CHAMPVA is a Department of Veterans Affairs program whereas Tri-Care is a regionally managed health care program for active duty and retired members of the uniformed services, their families and survivors. In some cases a veteran may appear to be eligible for both/either program on paper.

However, military retirees, or the spouse of a veteran who was killed in action, are and will always be Tri-Care beneficiaries.

90. Pursuant to 38 U.S.C. §8126, and the regulations based thereon, and contracts the Veterans Administration has with manufacturers, drugs furnished to the Veterans' Administration by drug manufacturers must be furnished at the best price.

91. The VA and CHAMPUS/Tri-care operate in substantially similar ways to the Medicare and Medicaid programs, but primarily for the benefit of military veterans, their spouses (or widowed spouses) and other beneficiaries.

92. As a direct, proximate and intended result of the conduct of the Defendants' alleged herein in violation of the federal false claims act and the analogous laws of the Plaintiff States, the CHAMPVA program has been damaged.

F. Indian Health Service

93. The Indian Health Service is responsible for providing comprehensive health services to more than 1,400,000 Americans. It is administered by the Department of Health and Human Services pursuant to 42 U.S.C. 2008 *et seq.* The statute authorizes the Secretary to enter into contracts with independent providers to furnish health services to Native Americans whenever the Secretary determines that independent providers can better meet the population's need.

G. State Legal Immigrant Assistance Grants

94. Relator is informed and believes and based thereon alleges that the United States also furnishes funds which several States use to pay for prescription drugs pursuant to State Legal Immigrant Assistance Grants ("SLIAG"), 8 U.S.C.A §1255A; 45 C.F.R. §402.10.

95. As a direct, proximate and intended result of the conduct of the Defendants' alleged herein in violation of the Federal False Claims Act and the analogous laws of the Plaintiff States, the SLIAG program has been damaged.

VII. CLAIMS FOR RELIEF

COUNT ONE

Violations of the Federal False Claims Act, 31 U.S.C. §3729(a)(1)(A) Presenting or Causing to be Presented False Claims

96. Plaintiff Klotz realleges and incorporates by reference each and every one of the foregoing paragraphs as if fully set forth herein.

97. This is a *qui tam* action brought by Klotz and the United States to recover treble damages, civil penalties and the cost of this action, under the Federal False Claims Act, 31 U.S.C. §3730 for Defendants' violations of 31 U.S.C. §3729 *et seq.*

98. The Federal False Claims Act, 31 U.S.C. §3729(a)(1)(A) provides:

> Liability for certain acts. Any person who--
>
> (A) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval.

Id.

99. By virtue of the above-described acts, among others, Defendants knowingly presented or caused to be presented false or fraudulent claims for payment or approval, and possibly continues to cause to be submitted false or fraudulent claims for payment or approval, directly or indirectly, to officers, employees or agents of the United States, in violation of 27 U.S.C. §3729(a)(1)(A).

100. For example, those false claims include claims for reimbursement for off-label/non-medically accepted prescriptions of Defendants' drug Intuniv which would not have

been submitted, and thereafter paid by the United States, but for the illegal practices of Defendants described in this Complaint.

101. Plaintiff United States, unaware of the falsity of the claims that the Defendants caused doctors, pharmacies, hospitals and other health care providers to make to the United States, and in reliance on the accuracy thereof, paid said doctors, hospitals, pharmacies and other health care providers for claims that would otherwise not have been allowed. These claims – prescription drug reimbursement claims for Defendants' drug Intuniv – were false as that term is defined by the Federal False Claims Act in that they were ineligible for reimbursement as described herein.

102. For those claims that Defendants submitted or caused to be submitted, it was foreseeable and in fact the intended result that those claims would be submitted. Further, at all times relevant to the Complaint, Defendants acted with the requisite scienter.

103. By reason of Defendants' unlawful practices, substantial numbers of doctors, hospitals, pharmacies and other health care providers in the United States have been induced to purchase substantial quantities of Defendants' drug Intuniv and these practices thus provided substantial profits to Defendants.

104. By reason of these unlawful practices by Defendants, as aforesaid, doctors, hospitals, pharmacies and other health care providers have been induced to purchase Defendants' drug Intuniv rather than recommending less expensive procedures or treatment options for their patients.

105. The amounts of the false or fraudulent claims to the United States were material. Plaintiff United States, being unaware of the falsity of the claims and/or statements caused to be

made by Defendants, and in reliance on the accuracy thereof paid and continues to pay for Defendants' unlawfully induced prescriptions.

106. It is believed that as a result of Defendants' violations of 31 U.S.C. §3729 (a)(1)(A), the United States has suffered substantial losses in an amount that exceeds tens of millions of dollars, and is entitled to treble damages under the False Claims Act, to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each such false claim presented or caused to be presented by Defendants.

107. Klotz is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Federal False Claims Act on behalf of himself and the United States.

COUNT TWO

Violations of the Federal False Claims Act, 31 U.S.C. §3729(a)(1)(B)
Creation or Use of False Statements or Records Material to a False Claim

108. Plaintiff Klotz realleges and incorporates by reference each and every one of the foregoing paragraphs as if fully set forth herein.

109. This is a *qui tam* action brought by Klotz and the United States to recover treble damages, civil penalties and the cost of this action, under the Federal False Claims Act, 31 U.S.C. §3730 for Defendants' violations of 31 U.S.C. §3729 *et seq.*

110. The Federal False Claims Act, 31 U.S.C. §3729(a)(1)(B) provides:

> Liability for certain acts. Any person who--
>
> > (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim

Id.

111. By virtue of the above-described acts, among others, Defendants knowingly made used or caused to be made or used false records or statements material to false claims, and possibly continues to do so, in violation of 27 U.S.C. §3729(a)(1)(B).

112. For example, claims for reimbursement for off-label prescriptions of Defendants' drug Intuniv would not have been submitted, and thereafter paid by the United States, but for the illegal practices of Defendants described in this Complaint including their false records and statements.

113. Plaintiff United States, unaware of the falsity of the records and/or statements which the Defendants made or caused doctors, pharmacies, hospitals and other health care providers to make, and in reliance on the accuracy of these records and/or statements, paid said doctors, hospitals, pharmacies and other health care providers for claims that would otherwise not have been allowed. These claims – prescription drug reimbursement claims for Defendants' drug Intuniv – were false as that term is defined by the Federal False Claims Act in that they were ineligible for reimbursement as described herein.

114. For those records and/or statements that Defendants made or used or caused to be made or used, it was foreseeable and in fact the intended result that those statements and/or records would result in the payment of false reimbursement claims for Defendants' drug Intuniv. Further, at all times relevant hereto, Defendants acted with the requisite scienter.

115. By reason of Defendants' unlawful practices, as aforesaid, substantial numbers of doctors, hospitals, pharmacies and other health care providers in the United States have been induced to prescribe and purchase substantial quantities of Defendants' drug Intuniv and thus provided substantial profits to Defendants. Moreover these purchases of Defendants' drug Intuniv occurred rather than purchases of less expensive procedures or treatment options for patients.

116. The amounts of the false or fraudulent claims caused to be paid pursuant to Defendants' false records and statements made or used or caused to be made or used to the United States were material. Plaintiff United States, being unaware of the falsity of the records and/or statements made or caused to be made by Defendants, and in reliance on the accuracy thereof, paid claims that Defendants knew to be false, as they intended.

117. It is believed that as a result of Defendants' violations of 31 U.S.C. §3729 (a)(1)(B), the United States has suffered substantial losses in an amount that exceeds tens of millions of dollars, and therefore is entitled to treble damages under the False Claims Act, to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each such false record and/or statement made or used or caused to be made or used by Defendants.

118. Klotz is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Federal False Claims Act on behalf of himself and the United States.

COUNT THREE

Violations of the Federal False Claims Act, 31 U.S.C. §3729(a)(1)(C) Conspiracy

119. Plaintiff Klotz realleges and incorporates by reference each and every one of the foregoing paragraphs as if fully set forth herein.

120. This is a *qui tam* action brought by Klotz and the United States to recover treble damages, civil penalties and the cost of this action, under the Federal False Claims Act, 31 U.S.C. §3730 for Defendants' violations of 31 U.S.C. §3729 *et seq.*

121. The Federal False Claims Act, 31 U.S.C. §3729(a)(1)(C) provides:

> Liability for certain acts. Any person who—
>
> (C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G); ...is liable to the United States Government for a civil penalty of not less

> than $ 5,500 and not more than $11,000, plus 3 times the amount of damages which the Government sustains because of the act of that person, ...
>
> *Id.*

122. In violation of 31 U.S.C. §3729(a)(1)(C), by the foregoing acts and omissions, Defendants conspired with physicians, paid consultants and others including but not limited to those physicians identified in this complaint to violate §3729(a)(1)(A)(B) and (G) in violation of the False Claims Act, 31 U.S.C. §3729(a)(1)(C).

123. By the foregoing acts and omissions, Defendants took actions in furtherance of their conspiracies, including but not limited to the payment of substantial sums of monies and/or illegal kickbacks to its co-conspirators as well as entering into unlawful contracts. Indeed, Defendants conspired to violate the AKS by unlawfully offering incentives to physicians and offering or receiving incentives from others that were in a position of authority to cause other physicians to write unnecessary prescriptions of Defendants' drug Intuniv, including for off-label uses. Said actions constitute violations of the Federal False Claims Act, 31 U.S.C. §3729(a)(1)(C). Defendants committed other overt acts set forth above in furtherance of that conspiracy, all in violation of the laws of and causing damage to the United States.

124. As a consequence of Defendants' violations of 31 U.S.C. §3729 (a)(1)(C), the United States has suffered substantial losses in an amount that exceeds tens of millions of dollars, and is entitled to treble damages under the False Claims Act, to be determined at trial, plus a civil penalty of $5,500 to $11,000 for each such false claim Defendants conspired to get paid or allowed.

125. Klotz is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Federal False Claims Act on behalf of himself and the United States.

COUNT FOUR

(District of Columbia False Claims Act)
(D.C. Code Ann. §§ 2-308.03 *et seq.*)

126. Plaintiff Klotz restates and incorporates each and every allegation above as if the same were fully set forth herein.

127. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the District of Columbia Government for payment or approval.

128. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the District of Columbia Government to approve and pay such false and fraudulent claims.

129. The District of Columbia Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

130. By reason of the Defendants' acts, the District of Columbia has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

131. Pursuant to D.C. Code Ann. § 2-308.14, the District of Columbia is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT FIVE

(California False Claims Act)
(Cal. Govt. Code §§ 12651 *et seq.*)

132. Plaintiff Klotz restates and incorporates each and every allegation above as if the same were fully set forth herein.

133. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the California State Government for payment or approval.

134. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the California State Government to approve and pay such false and fraudulent claims.

135. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

136. By reason of the Defendants' acts, the State of California has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

137. Pursuant to Cal. Govt. Code § 12651(a), the State of California is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT SIX

(Colorado Medicaid False Claims Act)
(Colo Rev, Stats. §25.5-4-305 *et seq*.)

138. Plaintiff Klotz restates and incorporates each and every allegation above as if the same were fully set forth herein.

139. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Colorado State Government for payment or approval.

140. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Colorado State Government to approve and pay such false and fraudulent claims.

141. The Colorado State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

142. By reason of the Defendant's acts, the State of Colorado has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

143. Pursuant to Colorado Revised Statutes § 25.5-4-305 *et seq* , the State of Colorado is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT SEVEN

(Connecticut False Claims Act)
Connecticut Medicaid False Claims Act
CHAPTER 319v Sec. 17b-301a et seq.

144. Plaintiff Klotz restates and incorporates each and every allegation above as if the same were fully set forth herein.

145. This is a claim for treble damages and penalties under the Connecticut Medicaid False Claims Act, Chapter 319v Sec. 17b-301a *et seq.*

146. By virtue of the acts described above, defendants knowingly presented or caused to be presented, to an officer or employee of the State of Connecticut, false or fraudulent claims for payment or approval under medical assistance programs administered by the Department of Social Services.

147. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to secure the payment or approval by the State of Connecticut of such false or fraudulent claims under medical assistance programs administered by the Department of Social Services.

148. By virtue of the acts described above, defendants conspired with each other and with others to defraud the State of Connecticut by securing the allowance or payment of a false or fraudulent claim under medical assistance programs administered by the Department of Social Services.

149. The Connecticut State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

150. By reason of the defendants' acts, the State of Connecticut has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

151. The State of Connecticut is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT EIGHT

(Delaware False Claims and Reporting Act)
(Del Code Ann. tit. 6, §§ 1201 *et seq.*)

152. Plaintiff Klotz restates and incorporates each and every allegation above as if the same were fully set forth herein.

153. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Delaware State Government for payment or approval.

154. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Delaware State Government to approve and pay such false and fraudulent claims.

155. The Delaware State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

156. By reason of the Defendant's acts, the State of Delaware has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

157. Pursuant to Del. Code Ann. tit. 6, § 1201(a), the State of Delaware is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and

every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT NINE

(Florida False Claims Act)
(Fla. Stat. Ann. §§ 68.081 *et seq.*)

158. Plaintiff Klotz restates and incorporates each and every allegation above as if the same were fully set forth herein.

159. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Florida State Government for payment or approval.

160. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Florida State Government to approve and pay such false and fraudulent claims.

161. The Florida State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

162. By reason of the Defendant's acts, the State of Florida has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

163. Pursuant to Fla. Stat. Ann. § 68.082(2), the State of Florida is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT TEN

(Georgia False Medicaid Claims Act)
(Ga. Code. Ann. §§ 49-4-168.1 *et seq.*)

164. Plaintiff Klotz restates and incorporates each and every allegation above as if the same were fully set forth herein.

165. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Georgia State Government for payment or approval.

166. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Georgia State Government to approve and pay such false and fraudulent claims.

167. The Georgia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

168. By reason of the Defendants' acts, the State of Georgia has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

169. Pursuant to Ga. Code. Ann. § 49-4-168.1(a), the State of Georgia is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT ELEVEN

(Hawaii False Claims Act)
(Haw. Rev. Stat. §§ 661-21 *et seq.*)

170. Plaintiff Klotz restates and incorporates each and every allegation above as if the same were fully set forth herein.

171. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Hawaii State Government for payment or approval.

172. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Hawaii State Government to approve and pay such false and fraudulent claims.

173. The Hawaii State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

174. By reason of the Defendants' acts, the State of Hawaii has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

175. Pursuant to Haw. Rev. Stat. § 661-21(a), the State of Hawaii is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT TWELVE

(Illinois Whistleblower Reward and Protection Act)
(740 l. Comp. Stat. §§ 175/1 *et seq.*)

176. Plaintiff Klotz restates and incorporates each and every allegation above as if the same were fully set forth herein.

177. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Illinois State Government for payment or approval.

178. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Illinois State Government to approve and pay such false and fraudulent claims.

179. The Illinois State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

180. By reason of the Defendants' acts, the State of Illinois has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

181. Pursuant to 740 Ill. Comp. Stat. § 175/3(a), the State of Illinois is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT THIRTEEN

(Indiana False Claims and Whistleblower Protection Act)
(Ind. Code §§ 5-11-5.5-1 *et seq.*)

182. Plaintiff Klotz restates and incorporates each and every allegation above as if the same were fully set forth herein.

183. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Indiana State Government for payment or approval.

184. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Indiana State Government to approve and pay such false and fraudulent claims.

185. The Indiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

186. By reason of the Defendants' acts, the State of Indiana has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

187. Pursuant to Ind. Code § 5-11-5.5-2(b), the State of Indiana is entitled to three times the amount of actual damages plus at least $5,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT FOURTEEN

(Louisiana Medical Assistance Programs Integrity Law)
(La. Rev. Stat. Ann. §§ 46:439.1 *et seq.*)

188. Plaintiff Klotz restates and incorporates each and every allegation above as if the same were fully set forth herein.

189. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Louisiana State Government for payment or approval.

190. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Louisiana State Government to approve and pay such false and fraudulent claims.

191. The Louisiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

192. By reason of the Defendants' acts, the State of Louisiana has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

193. Pursuant to La. Rev. Stat. Ann. § 46:438.6, the State of Louisiana is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT FIFTEEN

(Massachusetts False Claims Law)
(Mass. Gen. Laws ch. 12, §§ 5A *et seq.*)

194. Plaintiff Klotz restates and incorporates each and every allegation above as if the same were fully set forth herein.

195. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Massachusetts Commonwealth Government for payment or approval.

196. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Massachusetts Commonwealth Government to approve and pay such false and fraudulent claims.

197. The Massachusetts Commonwealth Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

198. By reason of the Defendants' acts, the Commonwealth of Massachusetts has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

199. Pursuant to Mass. Gen. Laws ch. 12, § 5B, the Commonwealth of Massachusetts is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT SIXTEEN

(Michigan Medicaid False Claims Act)
(Mich. Comp. Laws §§ 400.601 *et seq.*)

200. Plaintiff Klotz restates and incorporates each and every allegation above as if the same were fully set forth herein.

201. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the State of Michigan for payment or approval.

202. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Michigan State Government to approve and pay such false and fraudulent claims.

203. The Michigan State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

204. By reason of the Defendants' acts, the State of Michigan has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

205. Pursuant to Mich. Stat. § 400.612, the State of Michigan is entitled to a civil penalty equal to the full amount received by the person benefiting from the fraud plus triple the amount of damages suffered by the state as a result of the conduct by the person.

COUNT SEVENTEEN

(Minnesota False Claims Act)
(Minn, Stat, §15C.01 *et seq.*)

206. Plaintiff Klotz restates and incorporates each and every allegation above as if the same were fully set forth herein.

207. This is a claim for treble damages and penalties under the Minnesota False Claims Act, Minn, Stat, §15C.01 *et seq.*

208. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, to an officer or employee of the State of Minnesota and/or political subdivisions, false or fraudulent claims for payment or approval.

209. By virtue of the acts described above, defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to get false or fraudulent claims paid ort approved by the State of Minnesota and/or its political subdivisions.

210. By virtue of the acts described above, defendants knowingly conspired to either: 1) present a false or fraudulent claim to the State of Minnesota or a political subdivision for

payment or approval; or, 2) makes, use, or cause to be made or used a false record or statement to obtain payment or approval of a false or fraudulent claim

211. The Minnesota State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for defendants' illegal inducements and/or business practices.

212. By reason of the Defendants' acts, the State of Minnesota has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

213. The State of Minnesota is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT EIGHTEEN

(Montana False Claims Act)
(Mont. Code, Ch. 465)

214. Plaintiff Klotz restates and incorporates each and every allegation above as if the same were fully set forth herein.

215. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the State of Montana for payment or approval.

216. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Montana State Government to approve and pay such false and fraudulent claims.

217. The Montana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid

and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

218. By reason of the Defendants' acts, the State of Montana has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

219. Pursuant to Mont. Code, Ch. 465, the State of Montana is entitled to a civil penalty equal to the full amount received by the person benefiting from the fraud plus triple the amount of damages suffered by the state as a result of the conduct by the person.

COUNT NINETEEN

(Nevada False Claims Act)
(Nev. Rev. Stat. §§ 357.010 *et seq.*)

220. Plaintiff Klotz restates and incorporates each and every allegation above as if the same were fully set forth herein.

221. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Nevada State Government for payment or approval.

222. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Nevada State Government to approve and pay such false and fraudulent claims.

223. The Nevada State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

224. By reason of the Defendant's acts, the State of Nevada has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

225. Pursuant to Nev. Rev. Stat. § 357.040(1), the State of Nevada is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT TWENTY

(New Hampshire False Claims Act)
(N.H. Rev. Stat. Ann. § 167:61-b)

226. Plaintiff Klotz restates and incorporates each and every allegation above as if the same were fully set forth herein.

227. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the New Hampshire State Government for payment or approval.

228. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Hampshire State Government to approve and pay such false and fraudulent claims.

229. The New Hampshire State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

230. By reason of the Defendant's acts, the State of New Hampshire has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

231. Pursuant to § 167:61-b, the State of New Hampshire is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or

fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT TWENTY-ONE

(New Jersey False Claims Act)
(N.J. Stat. Ann. §§ 2A:32C-1 *et seq.*)

232. Plaintiff Klotz restates and incorporates each and every allegation above as if the same were fully set forth herein.

233. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the New Jersey State Government for payment or approval.

234. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Jersey State Government to approve and pay such false and fraudulent claims.

235. The New Jersey State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

236. By reason of the Defendants' acts, the State of New Jersey has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

237. Pursuant to N.J. Stat. Ann. § 2A:32C-3, the State of New Jersey is entitled to three times the amount of actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT TWENTY-TWO

(New Mexico Fraud Against Tax Payers Act)
(N.M. Stat. Ann. §§ 44-9-1 *et seq.*)

238. Plaintiff Klotz restates and incorporates each and every allegation above as if the same were fully set forth herein.

239. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the New Mexico State Government for payment or approval.

240. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New Mexico State Government to approve and pay such false and fraudulent claims.

241. The New Mexico State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

242. By reason of the Defendant's acts, the State of New Mexico has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

243. Pursuant to N.M. Stat. Ann. § 44-9-3, the State of New Mexico is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT TWENTY-THREE

(New York False Claims Act)
(N.Y. State Fin. Law §§ 187 *et seq.*)

244. Plaintiff Klotz restates and incorporates each and every allegation above as if the same were fully set forth herein.

245. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the New York State Government for payment or approval.

246. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the New York State Government to approve and pay such false and fraudulent claims.

247. The New York State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

248. By reason of the Defendants' acts, the State of New York has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

249. Pursuant to N.Y. State Fin. Law § 189, the State of New York is entitled to three times the amount of actual damages plus the maximum penalty of $12,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT TWENTY-FOUR

(North Carolina False Claims Act)
(N.C. Gen. Stat. §§1-605 *et seq.)*

250. Plaintiff Klotz restates and incorporates each and every allegation above as if the same were fully set forth herein.

251. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the North Carolina State Government for payment or approval.

252. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the North Carolina State Government to approve and pay such false and fraudulent claims.

253. By virtue of the acts described above, Defendants conspired with each other and with others to defraud North Carolina by inducing the North Carolina State Government to pay or approve false or fraudulent claims.

254. The North Carolina State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

255. By reason of the Defendants' acts, the State of North Carolina has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

256. Pursuant to N.C. Gen. Stat. §§1-605 *et seq.*, The State of North Carolina is entitled to three times the amount of the actual damages plus the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by defendants.

COUNT TWENTY-FIVE

(Violations of the Oklahoma Medicaid False Claims Act)
(3 Okla. St. Ann. §§ 5053 *et seq.*)

257. Plaintiff Klotz restates and incorporates each and every allegation above as if the same were fully set forth herein.

258. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Oklahoma State Government for payment or approval.

259. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Oklahoma State Government to approve and pay such false and fraudulent claims.

260. The Oklahoma State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

261. By reason of Defendants' acts, the State of Oklahoma has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

262. Pursuant to 63 Okl. St. Ann. § 5053.1(B), the State of Oklahoma is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT TWENTY-SIX

(The State False Claims Act (Rhode Island)
(R.I. Gen. Laws §§ 9-1.1-1 *et seq.*)

263. Plaintiff Klotz restates and incorporates each and every allegation above as if the same were fully set forth herein.

264. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Rhode Island State Government for payment or approval.

265. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Rhode Island State Government to approve and pay such false and fraudulent claims.

266. The Rhode Island State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

267. By reason of the Defendants' acts, the State of Rhode Island has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

268. Pursuant to R.I. Gen. Laws § 9-1.1-3, the State of Rhode Island is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT TWENTY-SEVEN

(Tennessee Medicaid False Claims Act)
(Tenn. Code Ann. §§ 71-5-181 *et seq.*)

269. Plaintiff Klotz restates and incorporates each and every allegation above as if the same were fully set forth herein.

270. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Tennessee State Government for payment or approval.

271. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Tennessee State Government to approve and pay such false and fraudulent claims.

272. The Tennessee State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

273. By reason of Defendants' acts, the State of Tennessee has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

274. Pursuant to Tenn. Code § 71-5-182(a)(1), the State of Tennessee is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT TWENTY-EIGHT

(Texas Medicaid Fraud Prevention Law)
(Tex. Hum. Res. Code Ann. § 36.002)

275. Plaintiff Klotz restates and incorporates each and every allegation above as if the same were fully set forth herein.

276. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Texas State Government for payment or approval.

277. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Texas State Government to approve and pay such false and fraudulent claims.

278. The Texas State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

279. By reason of the Defendants' acts, the State of Texas has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

280. Pursuant to Tex. Hum. Res. Code Ann. § 36.002, the State of Texas is entitled to two times the amount of actual damages plus the maximum penalty of $15,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT TWENTY-NINE

(Virginia Fraud Against Taxpayers Act)
(Va. Code Ann. §§ 8.01-216.1 *et seq.*)

281. Plaintiff Klotz restates and incorporates each and every allegation above as if the same were fully set forth herein.

282. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the State of Virginia for payment or approval.

283. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the State of Virginia to approve and pay such false and fraudulent claims.

284. The State of Virginia , unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

285. By reason of Defendants' acts, the State of Virginia has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

286. Pursuant to Va. Code § 8.01-216.3(A), the State of Virginia is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

COUNT THIRTY

(Wisconsin False Claims for Medical Assistance Law)
(Wisc. Stat. § 20.931)

287. Plaintiff Klotz restates and incorporates each and every allegation above as if the same were fully set forth herein.

288. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Wisconsin State Government for payment or approval.

289. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the Wisconsin State Government to approve and pay such false and fraudulent claims.

290. The Wisconsin State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

291. By reason of the Defendants' acts, the State of Wisconsin has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

292. Pursuant to Wisc. Stat. § 20.931(2), the State of Wisconsin is entitled to three times the amount of actual damages plus the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

VIII. DEMANDS FOR RELIEF

WHEREFORE, Relator, on behalf of the United States Government and the Plaintiff States, demands judgment against the above-named Defendants as follows:

1. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the United States has sustained because of defendants' actions, plus a civil penalty of not less than $5,500 and not more than $11,000 for each violation of 31 U.S.C. §3729 et seq.;

2. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of California has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Cal. Govt. Code §12651(a);

3. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Colorado has sustained because of defendants' actions, plus the maximum civil penalty of $10,000 for each violation of the Colorado Medicaid False Claims Act, C.R.S. §25.5-4-304, et seq.;

4. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Connecticut has sustained because of defendants' actions, plus the maximum civil penalty of $10,000 for each violation of CHAPTER 319v Sec. 17b-301a et seq.;

5. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Delaware has sustained because of defendants' actions, plus a civil penalty of $11,000 for each violation of 6 Del. C. §1201(a);

6. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Florida has sustained because of defendants' actions, plus a civil penalty of $11,000 for each violation of Fla. Stat. Ann. §68.082;

7. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Hawaii has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Haw. Rev. Stat. §661-21(a);

8. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Illinois has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of 740 Ill. Comp. Stat. §175/3(a);

9. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Massachusetts has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Mass. Gen. L. Ch. 12 §5B;

10. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Minnesota has sustained because of defendants' actions, plus the maximum civil penalty of $11,000 for each violation of Minn. Stat. § 15C.01 *et seq*;

11. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Nevada has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Nev. Rev. Stat. Ann. §357.040(1);

12. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of New Mexico has sustained because of defendants' actions, plus civil penalties for each violation of N.M. Stat. Ann. §27-14-1 et seq. and N.M. Stat. Ann. §44-9-1 et seq;

13. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of North Carolina has sustained because of defendants' actions plus a civil penalty of $11,000 for each violation of N.C. Gen. Stat. §§1-605 et seq.;

14. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Tennessee has sustained because of defendants' actions, plus a civil penalty for each violation of Tenn. Code Ann. §71-5-182(a);

15. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Texas has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Tex. Hum. Res. Code Ann. §36.002;

16. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the Commonwealth of Virginia has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of Va. Code Ann. §8.01-216.3(a);

17. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the District of Columbia has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of D.C. Code Ann. § 2-308.14(a);

18. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Georgia has sustained because of defendants' actions, plus a civil penalty of $11,000 for each violation of O.C.G.A §§ 49-4-168 et seq;

19. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Indiana has sustained because of defendants' actions, plus civil penalties for each violation of I.C. §5-11-5.5;

20. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Louisiana has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of La. Rev. Stat. §437 et. seq.;

21. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Michigan has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of MCL 400.601 et seq.;

22. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of New Hampshire has sustained because of defendants' actions, plus civil penalties for each violation of N.H. Rev. Stat. Ann. §167:61-b(I);

23. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of New York has sustained because of defendants' actions, plus a civil penalty of $12,000 for each violation of N.Y. State Fin. §§ 187 et seq.;

24. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Oklahoma has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of 2007 OK. ALS 137;

25. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of New Jersey has sustained because of defendants' actions, plus civil penalties for each violation of N.J. Stat. §2A:32C-1 et seq.;

26. that this Court enter judgment against defendants in an amount equal to three times the amount of damages the State of Rhode Island has sustained because of defendants' actions, plus civil penalties for each violation of R.I. Gen. Laws §9-1.1-1 et seq.;

27. that this Court enter judgment against defendants in an amount equal to three times the amount of damages Wisconsin has sustained because of defendants' actions, plus a civil penalty of $10,000 for each violation of the Wis. Stat. §20.931 et seq.;

28. that this court enter judgment against defendants in an amount equal to three times the amount of damages Montana has sustained because of the defendants' actions, plus a civil penalty of $10,000 for each violation of the Montana False Claims Act, Mont. Code Ann., § 17-8-401 *et seq.*;

29. that Plaintiff be awarded all costs of this action, including attorneys' fees and expenses;

30. that this Court enter judgment against Defendants for Defendants' violations of the FCA; and

31. that Plaintiff recovers such other relief as the Court deems just and proper, or that is necessary to make Plaintiff whole.

TRIAL BY JURY

Relator hereby demands a trial by jury as to all issues.

BY: _____

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Dated: October 8, 2010